

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)	
FENFLURAMINE/DEXFENFLURAMINE))	MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)	
)	
)	
THIS DOCUMENT RELATES TO:)	
)	
SHEILA BROWN, et al.)	CIVIL ACTION NO. 99-20593
v.)	
)	
AMERICAN HOME PRODUCTS)	2:16 MD 1203
CORPORATION)	

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9470

Bartle, J.

July 19, 2016

The Estate of Nina M. Winn ("Estate"), a representative claimant under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether the Estate has demonstrated a reasonable medical basis to support its claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify Diet Drug Recipients for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to the Diet Drug Recipient's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to representative claimants where the Diet Drug

(continued...)

To seek Matrix Benefits, a representative claimant³ must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The representative claimant completes Part I of the Green Form. Part II is completed by an attesting physician, who must answer a series of questions concerning the Diet Drug Recipient's medical conditions that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, if the representative claimant is represented by an attorney, the attorney must complete Part III.

In January, 2015, Nina M. Winn ("Ms. Winn") submitted a Green Form to the Trust, signed by the attesting physician, Marta C. Sayers, M.D.⁴ Based on an echocardiogram dated December 2, 2002, Dr. Sayers attested in Part II of the Green Form that

2. (...continued)

Recipients were diagnosed with serious VHD, they took the drugs for 61 days or longer, and they did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to representative claimants where the Diet Drug Recipients were registered as having only mild mitral regurgitation by the close of the Screening Period, they took the drugs for 60 days or less, or they were diagnosed with conditions that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Under the Settlement Agreement, representative claimants include estates, administrators or other legal representatives, heirs, or beneficiaries. See Settlement Agreement § II.B.

4. According to the Trust's Statement of the Case, the representative claimant for the Estate was Ms. Winn's son, Charles Enoch, even though Mr. Enoch had yet to be appointed as legal representative of the Estate. In a later submission, the Trust stated that Eldon Ray James is the Executor of the Estate.

Ms. Winn suffered from moderate mitral regurgitation and had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™.⁵ Based on such findings, the Estate would be entitled to Matrix A-1, Level III benefits⁶ in the amount of \$740,956.

Dr. Sayers also attested that Ms. Winn did not suffer from aortic stenosis or mitral annular calcification. Under the Settlement Agreement, the presence of aortic stenosis, which is defined as "[a]ortic stenosis with an aortic valve area < 1.0 square centimeter by the Continuity Equation," requires the payment of reduced Matrix Benefits for a claim based on damage to the aortic valve. Settlement Agreement § IV.B.2.d.(2)(c)i)e). Similarly, under the Settlement Agreement, the presence of mitral annular calcification requires the payment of reduced Matrix Benefits for a claim based on damage to the mitral valve. See id. § IV.B.2.d.(2)(c)ii)d).

5. Dr. Sayers also attested that Ms. Winn had moderate aortic regurgitation, an abnormal left atrial dimension, an abnormal left ventricular end-systolic dimension, a reduced ejection fraction in the range of 50% to 60%, and New York Heart Association Functional Class II symptoms. These conditions are not at issue in this claim.

6. Under the Settlement Agreement, a representative claimant is entitled to Level III benefits if the Diet Drug Recipient suffered from "left sided valvular heart disease requiring . . . [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." See Settlement Agreement § IV.B.2.c.(3)(a).

In or around May, 2015, the Trust forwarded the claim for review by Zuyue Wang, M.D., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Wang concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Winn did not have aortic stenosis as defined by the Settlement Agreement. Specifically, Dr. Wang calculated Ms. Winn's aortic valve area as 0.7 cm^2 by the Continuity Equation, which is less than the one square centimeter threshold established by the Settlement Agreement. In addition, Dr. Wang concluded that Ms. Winn's echocardiogram demonstrated the presence of mitral annular calcification. In support of this conclusion, Dr. Wang stated:

There is no mitral annular calcification in the posterior mitral annulus, however, there is significant aortic annular calcification extending onto [the] anterior mitral leaflet which is consistent with radiation[-]induced valvulopathy as indicated in the operative report.⁷

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination that the Estate was

7. Dr. Wang also determined that there was no reasonable medical basis for finding that Ms. Winn had at least moderate mitral regurgitation between the commencement of Diet Drug use and the end of the Screening Period, i.e., before January 3, 2003 for echocardiograms performed outside of the Trust's Screening Program and before July 3, 2003 for echocardiograms performed in the Trust's Screening Program. See Settlement Agreement § I.49. The finding would also requirement the payment of reduced Matrix Benefits. See id. § IV.B.2.d.(2)(a). Given our disposition with respect to the presence of aortic stenosis and mitral annular calcification, we need not address this issue.

entitled only to Matrix B-1, Level III benefits.⁸ Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), the Estate contested this adverse determination.⁹ In contest, the Estate stated in general terms that it contested "the findings made by the Auditing Cardiologist." In support of its contest, the Estate submitted a letter from Andrew J. Maiolo, M.D. Neither the Estate nor Dr. Maiolo, however, addressed the auditing cardiologist's findings regarding the presence of aortic stenosis and mitral annular calcification.¹⁰ Instead, they only raised specific challenges to Dr. Wang's determination that there was no reasonable medical basis for finding that Ms. Winn had at least moderate mitral regurgitation between the commencement of Diet Drug use and the end of the Screening Period

8. As the Trust does not contest the Estate's entitlement to Level III benefits, the only issue before us is whether the Estate is entitled to payment on Matrix A-1 or Matrix B-1.

9. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to the Estate's claim.

10. The Estate also requested that the Trust provide "data regarding the percentage of claims audited by Dr. Wang that were denied or reduced to Matrix B." The Estate, however, acknowledged that the Audit Rules do not permit discovery. See Audit Rule 41.

The Trust then issued a final post-audit determination, again determining that the Estate was entitled only to Matrix B-1, Level III benefits. The Estate disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the Estate's claim should be paid. On December 30, 2015, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 9454 (Dec. 30, 2015).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. The Estate then served a response upon the Special Master. The Trust submitted a reply on March 14, 2016.

The issue presented for resolution of this claim is whether the Estate has met its burden of proving that there is a reasonable medical basis for finding that Ms. Winn did not suffer from aortic stenosis as defined by the Settlement Agreement or from mitral annular calcification. See Audit Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in the Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on

the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order directed the Trust to pay the claim in accordance with the Settlement Agreement.

See id. Rule 38(b).

In support of its claim, the Estate argues that it adequately challenged the auditing cardiologist's findings as to aortic stenosis and mitral annular calcification and states that, "[r]ather than submit additional evidence in that regard, Claimant feels confident resting on Dr. Sayers' findings and submits that Dr. Sayers had a reasonable medical basis therefor." In response, the Trust argues that the Estate has not established a reasonable medical basis for the attesting physician's representations that Ms. Winn did not have aortic stenosis and mitral annular calcification and that the Estate failed adequately to dispute the auditing cardiologist's findings.

After reviewing the entire Show Cause Record, we find the Estate failed to contest adequately the findings of the auditing cardiologist with respect to the presence of aortic stenosis and mitral annular calcification. As noted, the Settlement Agreement requires that a claim for damage to the aortic valve be reduced to the B Matrix if the Diet Drug Recipient had aortic stenosis, which is defined as aortic stenosis with an aortic valve area < 1.0 square centimeter by the Continuity Equation. See Settlement Agreement § IV.B.2.d.(2)(c)i)e).

Similarly, the Settlement Agreement requires that a claim for damage to the mitral valve be reduced to the B Matrix if the Diet Drug Recipient had mitral annular calcification. See id. § IV.B.2.d. (2) (c)ii)d).

The auditing cardiologist specifically determined that Ms. Winn's December 2, 2002 echocardiogram revealed the presence of aortic stenosis, as defined by the Settlement Agreement, as well as mitral annular calcification. Despite the opportunity in the contest period to present additional evidence in support of the claim, the Estate rests only on the answers provided in Ms. Winn's Green Form by the attesting physician, Dr. Sayers. Mere disagreement with the auditing cardiologist without identifying specific errors by the auditing cardiologist, however, is insufficient to meet a representative claimant's burden of proof.

Where, as here, the auditing cardiologist specifically determines the presence of reduction factors on the echocardiogram at issue, a representative claimant may not rest or rely solely on the Green Form representations. Audit Rule 18 states: "In contesting any aspect of the Post-Audit determination based on any finding(s) of the Auditing Cardiologist, the claimant shall state the factual reasons for the contest and identify any alleged errors by the Auditing Cardiologist." Audit Rule 18(b) (emphasis added). Here, the Estate did not state any factual reasons for its contest of the auditing cardiologist's

findings, and it did not identify any alleged errors by the auditing cardiologist. Instead, the Estate stated only that it did not intend to submit additional evidence and that the Estate "feels confident resting on Dr. Sayers' findings." Thus, the Estate has failed to meet its burden of demonstrating that there is a reasonable medical basis for the attesting physician's findings that Ms. Winn did not have aortic stenosis or mitral annular calcification. Accordingly, the Estate's Level III claim based on surgery to Ms. Winn's aortic and mitral valves properly was reduced to Matrix B-1.

For the foregoing reasons, we conclude that the Estate has not met its burden of proving that there was a reasonable medical basis for finding that Ms. Winn did not have aortic stenosis as defined by the Settlement Agreement or mitral annular calcification. Therefore, we will affirm the Trust's denial of the Estate's claim for Matrix A benefits.